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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,141

05/17/2005

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EXAMINER

HOBBS, MICHAEL L

ART UNIT

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,141	Applicant(s) CHOI ET AL.	
	Examiner MICHAEL HOBBS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-11 and 13-16 is/are rejected.
- 7) ☒ Claim(s) 6 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/17/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

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later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (US 6,287,340 B1) in view of Bull (US 3,824,841).

6. For claim 1, Altman teaches a plurality of reactor tubes (col. 10 lines 63-66, 22) with a compressive strain motor or load cell (40) with a ball screw or Teflon™ bearings that are attached to the rotational shaft by a set of screws (col. 15 lines 55-57). Altman further teaches that the bioreactor has an upper anchor (24, 46) that is combined with the bearings to apply a compressive force to the cells. The reactor tubes have a lower anchor (32) that includes a shear motor (30) and a power transmitting means (36). However, Altman is silent regarding “teeth” on the reactor tube.

7. Bull teaches a device and method for studying the sedimentation characteristics of whole blood by using a centrifuge. For claim 1, Bull teaches that the tube (16) containing a blood sample are inserted into a tube holder (46) with a pinion wheel (48) that interacts with a spur wheel (38) to rotate the tube around its own axis (col. 10 lines 22-25 & 28-32, Abstract). While the pinion wheel is not at the bottom of the tube, it is within the skills of one of ordinary skill in the art to move the pinion wheel and spur to the bottom of the tube holder in order to rotate the blood sample. Further, it would be obvious to one of ordinary skill in the art to employ the pinion wheel and spur as suggested by Bull in order to rotate the tubes of Altman. The suggestion for doing so at the time would

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have been in order to generate a force of 6.25 to 8 G's on the sample within the tube (col. 9 lines 29-31). Refer to MPEP § 2144.04 VI C.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (US 6,287,340 B1) in view of Bull (US 3,824,841) and in further view of Ammann et al. (US 2002/0098117 A1).

9. For claim 5, Altman teaches that the lower anchor mount has a smaller diameter with an upper, larger diameter and a fitting groove in the anchor plate (Fig. 2). Altman and Bull are silent regarding bearings in the lower mount.

10. Ammann teaches an incubator with an automated diagnostic analyzer for performing multiple diagnostic assays simultaneously at multiple stations. For claim 5, teaches bearings (415) for the lower anchor portion of the mixing station (Fig. 11). The placement of bearings around a shaft to reduce friction between the anchor and base would be known to a skilled artisan. Therefore, it would be obvious to one of ordinary skill in the art to employ the bearings as suggested by Ammann in order to allow the reactor tube to freely rotate within the teachings of Altman.

11. Claims 2, 3 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (US 6,287,340 B1) in view of Bull (US 3,824,841) and in further view of Brimhall et al. (US 4,874,358).

12. For claims 2 and 3, Altman teaches that a main driving gear or motor is attached or fitted around an output shaft (Fig. 3), but remains silent regarding a

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hollow main shaft and an upper and lower strain gear. However, including a hollow main shaft to allow the top and bottom plates to freely rotate when the shear motor is on would be within the skills of one of ordinary skill in the art. Furthermore, the use of this type of shaft would reduce friction between the plates and the supporting shaft and would allow the device to be able to hold more reactor tubes to further increase throughput. Also, Altman and Bull are silent regarding a drive pulley.

13. Brimhall teaches a dual axis continuous flow centrifugation apparatus for the cultivation of cells. For claim 2, Brimhall teaches a lower shear gear (20) that is around the shaft (Fig. 1) and an upper shear gear (26) that is likewise around the motor shaft. The use of gears to rotate a bioreactor (or wheels on a bicycle as a related example) is known within the art and is one of finite number of solutions to transferring the momentum from motor to the reactor tube of the instant application. Therefore, it would be obvious to one of ordinary skill in the art to employ the use of an upper and lower gear as suggested by Brimhall in order to apply shear forces to the cartilage tissue of Altman and Bull. The suggestion for doing so at the time of the invention would have been to apply these shear forces to the tissue, in this case cartilage, in order to induce three-dimensional growth of the tissue with the goal of generating new tissue with a matrix similar to that grown *in vivo* (col. 2 lines 61-64).

14. With regards to claims 3, Brimhall teaches the limitations as discussed above plus that the lower gear is connected to a drive gear by a drive belt (24) or a drive pulley. There are a finite number of ways to drive a shaft such as being

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directly connected to the motor or using a "crank shaft" to rotate the shaft.

Therefore, it would be obvious to one of ordinary skill in the art to try the drive belt as suggested by Brimhall in order to rotate the reactor tubes of Altman and Bull in order to impart a shear force on the cartilage tissue within the tubes.

15. For claim 7, Altman teaches a reactor tube (22) with a cap (20) that seals the tube which has a compression guide hole with a compressing rod (Fig. 2).

For claim 8, silicone rubber was extended between the upper and lower Teflon™ in order to seal the tube (col. 15 lines 60-62). Also for claim 9, each tube is surrounded near the bottom with a clamp (Fig. 1) which is fully capable of preventing bending of the tube. For claim 10, the coral tissue support of Altman has a "column" shape since the support is in a tube (Fig. 2) and that coral is intrinsically porous.

16. Claims 4 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (US 6,287,340 B1) in view of Bull (US 3,824,841) and in further views of Brimhall et al. (US 4,874,358) , and Allington et al. (US 5,614,089).

17. For claim 4, Altman teaches a plurality of reactor tubes (col. 10 lines 63-66, 22) with a compressive strain motor or load cell (40) with a ball screw or Teflon™ bearings that are attached to the rotational shaft by a set of screws (col. 15 lines 55-57). Altman further teaches that the bioreactor has an upper anchor (24,46) that is combined with the bearings to apply a compressive force to the cells. The reactor tubes have a lower anchor (32) that includes a shear motor

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(30) and a power transmitting means (36). However, Altman is silent regarding a teeth on the tubes.

18. For claim 4, Bull teaches that the tube (16) containing a blood sample are inserted into a tube holder (46) with a pinion wheel (48) that interacts with a spur wheel (38) to rotate the tube around its own axis (col. 10 lines 22-25 & 28-32, Abstract). Also, the spur is mounted above the lower "anchor" of the tube holder (Fig. 2). While the pinion wheel is not at the bottom of the tube, it is within the skills of one of ordinary skill in the art to move the pinion wheel and spur to the bottom of the tube holder in order to rotate the blood sample. Further, it would be obvious to one of ordinary skill in the art to employ the pinion wheel and spur as suggested by Bull in order to rotate the tubes of Altman. The suggestion for doing so at the time would have been in order to generate a force of 6.25 to 8 G's on the sample within the tube (col. 9 lines 29-31). Refer to MPEP § 2144.04 VI C.

19. Altman and Bull are silent regarding a hollow guide or rotating means.

20. Brimhall teaches a lower shear gear (20) that is around the shaft (Fig. 1) and an upper shear gear (26) that is likewise around the motor shaft. The use of gears to rotate a bioreactor (or wheels on a bicycle as a related example) is known within the art and is one of finite number of solutions to transferring the momentum from motor to the reactor tube of the instant application. Therefore, it would be obvious to one of ordinary skill in the art to employ the use of an upper and lower gear as suggested by Brimhall in order to apply shear forces to the cartilage tissue of Altman and Bull. The suggestion for doing so at the time of the

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invention would have been to apply these shear forces to the tissue, in this case cartilage, in order to induce three-dimensional growth of the tissue with the goal of generating new tissue with a matrix similar to that grown *in vivo* (col. 2 lines 61-64).

21. Allington teaches an apparatus for the exchange of fluids for use with a chromatography device. With regard to claim 4, Allington teaches a guide that extends downward in the device as a guide for the fast action nut and screw (Fig. 6). The use of a ball screw with a guide allows for the nut and screw to remain in a vertical position to allow for the rapid-advance of the screw (col. 20 lines 62-65). Therefore, it would be obvious to one of ordinary skill in the art to employ the guide and screw as suggested by Allington in order to rapidly provide an even compression to the sample of Altman, Bull and Brimhall.

22. For claim 13, Altman teaches a reactor tube (22) with a cap (20) that seals the tube which has a compression guide hole with a compressing rod (Fig. 2). For claim 14, silicone rubber was extended between the upper and lower Teflon™ in order to seal the tube (col. 15 lines 60-62). Also for claim 15, each tube is surrounded near the bottom with a clamp (Fig. 1) which is fully capable of preventing bending of the tube. For claim 16, the coral tissue support of Altman has a "column" shape since the support is in a tube (Fig. 2) and that coral is intrinsically porous.

23. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (US 6,287,340 B1) in view of Bull (US 3,824,841) and in further

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views of Brimhall et al. (US 4,874,358) , Allington et al. (US 5,614,089) and Ammann et al. (US 2002/0098117 A1).

24. The combined teachings of Altman, Bull, Brimhall and Allington are silent regarding a bearing around the bottom of the reactor tube.

25. For claim 11, Ammann teaches bearings (415) for the lower anchor portion of the mixing station (Fig. 11). The placement of bearings around a shaft to reduce friction between the anchor and base would be known to a skilled artisan. Therefore, it would be obvious to one of ordinary skill in the art to employ the bearings as suggested by Ammann in order to allow the reactor tube to freely rotate within the teachings of Altman Bull, Brimhall and Allington.

Allowable Subject Matter

26. Claims 6 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

27. The following is a statement of reasons for the indication of allowable subject matter: the prior art fails to teach or fairly suggest a supporting spring with an upwardly extending fitting groove.

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Conclusion

28. Claims 1-5, 7-11 and 13-16 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

MLH

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